

FEB 20 2008

5.0 510(k) Summary**1. Sponsor**

SpineFrontier, Inc.
100 Cummings Center
Suite 240C
Beverly, MA 01915

Primary Contact: Thomas A. Carlson
Telephone: 1- 978-232-3990

Date Prepared: November 2, 2007

2. Indus Cervical Plate System:

Proprietary Name: **INDUS™ Anterior Cervical Plate System**
Common/Usual Name: Spinal Intervertebral Body Fixation Orthosis
Classification Name: Spinal Intervertebral Body Fixation Orthosis
(21 CFR 888.3060), Class II
Product Code: KWQ

3. Predicate Devices

K030866 – Synthes Spine - Anterior CSLP System

4. Device Description

The **INDUS™ Anterior Cervical Plate System** consists of a variety of shapes and sizes of plates, screws, locking crowns, and the associated instruments. The plates are available in four levels to accommodate one to four levels of fixation.

The screws come as self tapping or self drilling in various lengths and diameters. The **INDUS™ Anterior Cervical Plate System** components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136.

5. Intended Use

The **INDUS™ Anterior Cervical Plate System** is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in whom stability is desired following anterior cervical fusion. The levels of treatment range from C2 to C7. Indications include symptomatic cervical

spondylolisthesis, trauma (fracture or dislocation), spinal stenosis, deformities or curvatures (scoliosis, kyphosis and or lordosis), tumor, pseudoarthrosis, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), and re-operation for failed fusion or instability following surgery for above indications.

6. Technological Characteristics and Substantial Equivalent

The SpineFrontier **INDUS™ Anterior Cervical Plate System** and its predicate device have the same indications for use, operating principles and are made of the same materials.

Representative samples of the device underwent testing to demonstrate comparable function and performance characteristics to the predicate device.

7. Performance Testing

The **INDUS™ Anterior Cervical Plate System** meets the performance standard of ASTM Standard F1717-04, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model."



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SpineFrontier, Incorporated
% Mr. Tom Carlson
Chief Operating Officer
100 Cummings Center, Suite 240C
Beverly, MA 01915

Re: K073232
Trade/Device Name: Indus® Anterior Cervical Plate System, Model IM3xxx
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 22, 2008
Received: January 25, 2008

Dear Mr. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Tom Carlson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if Known): K073232

Indications For Use:

The **INDUS™ Anterior Cervical Plate System** is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in whom stability is desired following anterior cervical fusion. The levels of treatment range from C2 to C7. Indications include symptomatic cervical spondylolisthesis, trauma (fracture or dislocation), spinal stenosis, deformities or curvatures (scoliosis, kyphosis and or lordosis), tumor, pseudoarthrosis, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), and re-operation for failed fusion or instability following surgery for above indications.

Prescription Use: X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: _____
(Part 21 CFR 807 Subpart C)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K073232